DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Dental Products Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Dental Products Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 11, 2005, from 9:15 a.m. to 5:45 p.m., and on October 12, 2005, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC North/Gaithersburg, Ballroom Salons A and B, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Michael E. Adjodha, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–5283, ext. 123, e-mail: *mea@cdrh.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512518. Please call the Information Line for up-to-date information on this meeting.

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Agenda: On October 11, 2005, the committee will hear a presentation on the FDA Critical Path Initiative and a presentation by the Office of Surveillance and Biometrics in the Center for Devices and Radiological Health outlining their responsibility for the review of postmarket study design. Subsequently, on October 11 and 12, 2005, the committee will discuss and make recommendations on the classification of the following unclassified dental devices:

- Root canal cleanser, product code KJJ, intended to cleanse a root canal after endodontic instrumentation;
- Retraction cord, product code MVL, intended for temporary retraction and hemostasis of the gingival margin;
- Root apex locator, product code LQY, intended to measure the length of the root canal;
- Dental mouthguards, product code MQC, intended to provide protection against bruxism, teeth clenching, and grinding;
- Artificial saliva, product code LFD, intended for the relief of chronic and temporary xerostomia;
- Oral wound dressing, product code MGQ, intended to provide pain relief from aphthous ulcers, canker sores, and minor oral lesions; and
- Electrical anesthesia, product code LWM, intended, through the application of electrical current, to provide analgesia or anesthesia during dental procedures.

Also, on October 12, 2005, the committee will discuss and make recommendations regarding the over-the-counter (OTC) use of dental mouthguards. Background information for the topics, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting on the Internet at *http://www.fda.gov/cdrh/panelmtg.html.*

More information regarding product code classification can be accessed by visiting *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm* or by contact person. Material for the October 11 and 12 sessions will be posted on October 7, 2005.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by October 3, 2005. On October 11, 2005 and October 12, 2005, oral presentations from the public will be scheduled for approximately 30 minutes at the beginning of committee deliberations and for approximately 30 minutes near the end of the deliberations. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 3, 2005, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Conference Management Staff, 301–594–1283, ext. 113, at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: 9/6/05

September 6, 2005.

Scott Gottlieb,
Deputy Commissioner for Policy.

[FR Doc 05–????? Filed ??–??–05; 8:45 am]

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